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Washington State Board of Pharmacy

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No. 932 The Practice of Naturopathy Expands Drug Authority

The legislature recently expanded the authority of naturopathic physicians. The law was amended to replace the term "medicines of mineral, animal, and botanical origin" with the term "naturopathic medicines." Licensed naturopathic physicians may now prescribe, administer, dispense, and use legend drugs and controlled substances (CS) consistent with the practice of naturopathic medicine.

The specific medicines must be established by the Secretary of Health in rule. The prohibition on the use of CS was revised to permit the use of codeine and testosterone in Schedules III, IV, and V. The law includes education and training requirements for the use of CS.

The recent change builds on prior law and rules regarding naturopathy. In 1991, the Washington State Legislature recognized the practice of naturopathy in statute. The ability to prescribe, administer, dispense, and use certain medicines of mineral, animal, and botanical origin became part of the naturopathic physician's accepted scope of practice.

The following year, the state defined in rule the specific medicines the naturopathic physician may prescribe [(RCW 18.36A.020(10) and WAC 246-836-210(9)]. This included legend topical, local anesthetics, nondrug contraceptives except intrauterine devices, and intramuscular B-12 (cyanocobalamin) injections. Neoplastic drugs and CS were prohibited. The rule allowed the Secretary of Health to create a list of legend substances based on traditional botanical and herbal pharmacopeia. The first list was published in 1993 and updated in 2004, see *www.doh.wa.gov/pharmacy.*

There is a "draft" revision of WAC 246-836-210 – Authority to use, prescribe, dispense and order – to incorporate the most recent changes. The draft recognizes naturopathic physicians as primary care practitioners with authority to use legend drugs consistent with naturopathic medical practice. Naturopathic physicians may not prescribe for malignancies or neoplastic diseases. They also may not prescribe botulinum toxin or other inert substances used for cosmetic purposes. Naturopathic physicians may prescribe codeine and testosterone products in Schedules III, IV, and V.

Two new rules are being drafted to implement the law. The first describes the education and training requirements for naturopathic physicians to use, prescribe, dispense, or order CS. The second sets education and training requirements for a naturopathic physician to use intravenous therapy. The rule authorizes naturopathic physicians to use intramuscular, intravenous, subcutaneous, and intradermal injections.

The rule to implement the new law will be finalized in June 2007.

No. 933 Mission and Vision of the Board

The Washington State Board of Pharmacy met on February 28, 2007, to develop its strategic plan for the next two years. As part of the process the Board reviewed and reaffirmed its mission and vision.

Mission Statement: The mission of the Board of Pharmacy is to achieve the highest standards in the practice of pharmacy, to promote public health and safety and to effectively communicate with the Governor, Legislature, the Department of Health, the public and the profession.

Vision Statement: The Washington State Board of Pharmacy leads in creating a climate for the patient-focused practice of pharmacy.

Pharmacists inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality-based health care system.

As an outcome, the citizens of Washington state:

- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

No. 934 Board of Pharmacy Adopts New Rules on Sexual Misconduct

Sexual misconduct by a health care provider exploits the patient-practitioner relationship and violates public trust. On December 14, 2006, the Board adopted a new rule that defines specific acts and conduct as sexual misconduct. In addition, the rule documents standards for which allegation of sexual misconduct may be substantiated.

This rule, now found in Chapter 246-860 of the Washington Administrative Code, was adopted to protect patients' health and safety through clear guidelines that help pharmacists, pharmacy interns, and related personnel avoid sexual misconduct. In addition, the rule will educate consumers on inappropriate conduct by health care providers that may be grounds for discipline.

To review text of the new rule, visit "Rule Making Updates" on the Board's Web site *https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm.*

No. 935 Frequently Asked Questions

Q: How long must I keep proof of completing continuing education?

A: Four years. (WAC 246-12-200)

Q: Under what conditions can a Schedule II prescription be faxed to a pharmacy?

A: A facsimile prescription is okay as long as it is for a patient in a nursing home (RCW 18.51), boarding home (RCW 18.20), or adult family home (RCW 70.128). It can also be faxed for a patient enrolled in a hospice program. The fax needs to be sent directly from the practitioner (or agent) to the pharmacy. (RCW 69.50.308)

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

Changes in Medication Appearance Should Prompt Investigation

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at *https://nppes.cms.hhs.gov*.

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Q: Can a pharmacy assistant reconstitute antibiotics?

A: No. This duty is reserved to the pharmacy technician, intern, and pharmacist.

Q: Can I dispense a CS based on a prescription written by any practitioner in any state?

A: A Schedule II prescription can be accepted from any physician, osteopath, dentist, podiatrist, or veterinarian licensed in any state as long as they have an active license and Drug Enforcement Administration registration. Out-of-state "midlevel" practitioners do not have any prescriptive authority unless they are licensed by the Washington State Department of Health (RCW 69.41.030). A practitioner's license status can be checked through the "Provider Credential Search" link on the Board of Pharmacy Web site.

Q: What is the list of medical conditions for which a Schedule II stimulant can be prescribed?

A: Schedule II stimulants may only be prescribed for the following conditions (RCW 69.50.402):

- Multiple sclerosis (WAC 246-887-045)
- Narcolepsy
- Hyperkinesis
- Drug induced brain dysfunction
- Epilepsy
- Differential diagnostic psychiatric evaluation of depression
- Treatment of depression, which is refractory to other therapeutic modalities
- Clinical investigation of such drugs

No. 936 Board Member Appointments

Governor Chris Gregoire has named **Vandana Slatter** and **Dan Connolly** as members of the Board effective January 20, 2007 and February 16, 2007, respectively. Each appointment is for four years.

Dr Slatter has been licensed as a pharmacist in Washington for more than 16 years. She received her doctor of pharmacy degree from the University of Washington in 1990. Dr Slatter has practiced as a hospital pharmacist and devoted much of her career to clinical and strategic development in the pharmaceutical industry. Dr Slatter is an active member of both professional and public interest organizations.

Mr Connolly is the assistant vice president of pharmacy with Bartell Drugs. He has been a Washington licensed pharmacist for almost 40 years. Mr Connolly has worked as an independent community pharmacist as well as a hospital pharmacist, a pharmaceutical sales representative, and an executive for both small and large chain pharmacies. He is a member of Northwest Pharmacy Services and the Washington State Pharmacy Association.

The Department of Health is accepting applications for a future public member and a professional member on the Washington State Board of Pharmacy. These vacancies are set to be filled by the governor by January 19, 2008. The Board regulates the practice of pharmacy and enforces several laws aimed at the protection and promotion of the public health, safety, and welfare. For more information, please contact Doreen Beebe 360/236-4834 at the Board's office or link to "Board Info" at *https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/boardinfo.htm.*

No. 937 Recruitment for the Pharmacy Board Executive Director

Are you looking for a rewarding career in public health? The Washington State Department of Health is searching for a dynamic, high-energy, and committed public health professional for the position of executive director. The position works with the Board of Pharmacy, Board of Optometry, and the Veterinary Board of Governors. The position is also responsible for the Dispensing Optician and Orthotic/Prosthetic Advisory Committees. To obtain application information visit the Department of Health Web site at *http://www.doh.wa.gov/job_ann.htm.* Call Bonnie King at 360/236-4995 for additional information. The department will accept applications until April 30, 2007.

No. 938 Thank You and Farewell

The Board wishes to thank **Asaad Awan** for his contributions and service to the Washington State Board of Pharmacy for the past four years. As a board member and practicing pharmacist, Dr Awan demonstrated his dedication and devotion to the mission of the Board to achieve the highest standards in the practice of pharmacy and to promote public health and safety. We wish him well.

The *Washington State Board of Pharmacy News* is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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